



COPY

Patent ☒ Trademark ☒ Docket No. 000309.00202  
Serial No. 09/928,044 Filed August 11, 2001  
Inventor(s) Jon M. Bishay  
For: Method and Apparatus for Deploying A Percutaneous Probe  
By: TW:jm Due Date:

- |  |   |
|--|---|
| <input type="checkbox"/> Check in the amount of \$             | <input type="checkbox"/> Assignment w/PTO-1595 ( pgs.)                  |
| <input type="checkbox"/> Fee Transmittal for FY 2004           | <input type="checkbox"/> Priority Document ( )                          |
| <input type="checkbox"/> Resp. to Notice to File Missing Parts | <input type="checkbox"/> Replacement Drawing ( sheet(s))                |
| <input type="checkbox"/> Declaration & POA (executed)          | <input checked="" type="checkbox"/> IDS/PTO-1449 (153 Refs. - 3 Stacks) |
| <input type="checkbox"/> Pet. for Ext. of Time ( months)       | <input type="checkbox"/> Fee(s) Transmittal (Issue/Publication fees)    |
| <input type="checkbox"/> Election/Resp. to Rest. Requirement   | <input type="checkbox"/> RCE Transmittal                                |
| <input type="checkbox"/> Reply and Amendment                   | <input type="checkbox"/> Notice of Appeal                               |
| <input type="checkbox"/> Other:                                |   |

Receipt by the USPTO is hereby acknowledged of the papers filed as indicated in connection with the above-identified case.

PLEASE HAND-CARRY TO  
EXAMINER GEORGE EVANISKO  
CRYSTAL PLAZA 2  
ROOM 3B18

DOCKETED

000309.00202  
JUL 15 2004

Tel. 703 308-2612

JOC

mtt

7/15/4



COPY

Docket No. 000309.00202

**EXPEDITED HANDLING REQUESTED**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Jon M. Bishay.

SERIAL NO: 09/928,044

GAU: 3762

FILED: August 11, 2001

EXAMINER: George R. Evanisko

FOR: Method and Apparatus for Deploying A Percutaneous Probe

**RE-FILED**  
**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

MAIL STOP AMENDMENT  
COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA. 22313-1450

SIR:

Applicant wishes to disclose the following information.

The references attached hereto and listed on form PTO-1449 were previously submitted to the U.S. Patent and Trademark Office in an Information Disclosure Statement filed on August 5, 2002. In the Office Action dated December 3, 2003, the Examiner stated that the "information disclosure statement filed 8/5/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed....Several of the references listed were not in either parent case".

No item of information contained in this information disclosure statement was cited for the first time in any communication from a foreign patent office in any counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this statement.

Pursuant to the Examiner's comments in the Office Action dated December 3, 2003, applicants submit for consideration the references listed in form PTO-1449 attached hereto. The references that are deemed most pertinent by the applicant are marked with an "X" in the right hand column on form PTO-1449.

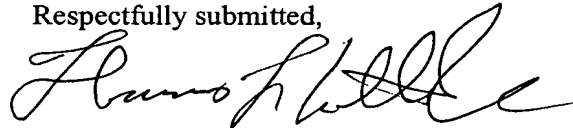
It is respectfully requested that the Examiner give expedited consideration to these disclosures so that applicant meets all certification requirements for statements under 37 CFR 1.97(e).

Pursuant Examiner Evanisko's suggestion in a telephone conference with applicant's attorney on July 12, 2004, it is respectfully requested that the U.S. patents cited on Form PTO-1449 attached hereto also be considered for applicant's copending application Serial No. 09/751,382. These references were included but not submitted with the Information Disclosure Statement filed on May 26, 2004.

If there are any questions relating to document or the references attached hereto, it is respectfully requested that the Examiner telephone the undersigned attorney to resolve such issues so that the attached references can be entered in the record before payment of the issue fee due on August 7, 2004.

Please charge the fee of \$180.00 and any additional fees that may be required to Deposit Account No. 23-2185. A duplicate copy of this sheet is enclosed.

Respectfully submitted,



Thomas Willis  
Attorney for Applicant  
Reg. No. 53,778

BLANK ROME LLP  
The Watergate 900 New Hampshire Ave., N.W.  
Washington, DC 20037  
(202) 772-5800



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)

*COMPLETE IF KNOWN*

|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

**Sheet 1 of 12**

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. | U.S. Patent or Application |                         | Name of Patentee or Inventor<br>of Cited Document | Date of<br>Publication or<br>Filing Date<br>of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Figures Appear |
|----------------------|-------------|----------------------------|-------------------------|---|--|--|
|                      |             | NUMBER                     | Kind Code<br>(if known) |   |  |  |
|                      |             | 6,539,264                  |                         | Bishay et al.                                     | 03/25/03   |  |
|                      |             | 6,493,592                  |                         | Leonard et al.                                    | 12/10/02   |  |
|                      |             | 6,549,797                  |                         | Leonard et al.                                    | 04/15/03   |  |
|                      |             | 6,556,869                  |                         | Leonard et al.                                    | 04/29/03   |  |
|                      |             | 6,552,927                  |                         | Bishay et al.                                     | 02/18/03   |  |
|                      |             | 6,549,810                  |                         | Leonard et al.                                    | 04/15/03   |  |
|                      |             | 6,516,226                  |                         | Bishay et al.                                     | 02/04/03   |  |
|                      |             | 6,560,491                  |                         | Bishay et al.                                     | 05/06/03   |  |
|                      |             | 3,030,959                  |                         | Grunert   | 04/24/62   |  |
|                      |             | 3,090,151                  |                         | Stewart et al.                                    | 05/21/63   |  |
|                      |             | 3,208,452                  |                         | Stern   | 09/28/65   |  |
|                      |             | 3,938,526                  |                         | Anderson et al.                                   | 02/17/76   |  |
|                      |             | 3,943,935                  |                         | Cameron   | 03/16/76   |  |
|                      |             | 3,983,881                  |                         | Wickham   | 10/05/76   |  |
|                      |             | 4,139,011                  |                         | Benoit et al.                                     | 02/13/79   |  |
|                      |             | 4,207,903                  |                         | O'Neill   | 06/17/80   |  |
|                      |             | 4,256,116                  |                         | Meretsky et al.                                   | 03/17/81   |  |
|                      |             | 4,281,659                  |                         | Farrar et al.                                     | 08/04/81   |  |
|                      |             | 4,431,000                  |                         | Butler et al.                                     | 02/14/84   |  |
|                      |             | 4,437,467                  |                         | Helfer et al.                                     | 03/20/84   |  |
|                      |             | 4,512,351                  |                         | Pohndorf  | 04/23/85   |  |
|                      |             | 4,556,064                  |                         | Pomeranz et al.                                   | 12/03/85   |  |
|                      |             | 4,583,549                  |                         | Manoli  | 04/22/86   |  |
|                      |             | 4,408,617                  |                         | Auguste   | 11/11/83   |  |
|                      |             | 4,262,672                  |                         | Kief  | 04/21/81   |  |
|                      |             | 4,541,432                  |                         | Molina-Negro et al.                               | 09/17/85   |  |
|                      |             | 5,702,359                  |                         | Hoffmann et al.                                   | 12/30/97   |  |
| Examiner             |             |                            |                         |   | Date Considered  |  |



INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTOA449 (Modified)  
(Use several sheets if necessary)

COMPLETE IF KNOWN

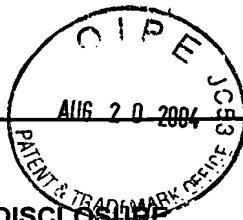
|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

**Sheet 2 of 12**

|  |  | U.S. Patent or Application |  |                  |          |
|--|--|----------------------------|--|------------------|----------|
|  |  | 4,685,466                  |  | Rau              | 08/11/87 |
|  |  | 4,686,996                  |  | Ulbrich          | 08/18/87 |
|  |  | 4,712,558                  |  | Kidd et al.      | 12/15/87 |
|  |  | 4,765,310                  |  | Deagle et al.    | 08/23/88 |
|  |  | 4,895,154                  |  | Bartelt et al. - | 01/23/90 |
|  |  | 4,934,371                  |  | Malis et al.     | 06/19/90 |
|  |  | 4,949,734                  |  | Bernstein        | 08/21/90 |
|  |  | 4,953,564                  |  | Berthelsen       | 09/04/90 |
|  |  | 5,012,811                  |  | Malis et al.     | 05/07/91 |
|  |  | 5,036,850                  |  | Owens            | 08/06/91 |
|  |  | 5,054,486                  |  | Yamada           | 10/08/91 |
|  |  | 5,094,242                  |  | Gleason et al.   | 03/10/92 |
|  |  | 5,117,826                  |  | Bartelt et al.   | 06/02/92 |
|  |  | 5,211,175                  |  | Gleason et al.   | 05/18/93 |
|  |  | 5,246,014                  |  | Williams et al.  | 09/21/93 |
|  |  | 5,255,691                  |  | Otten            | 10/26/93 |
|  |  | 5,269,304                  |  | Matthews         | 12/14/93 |
|  |  | 5,281,218                  |  | Imran            | 01/25/94 |
|  |  | 5,332,401                  |  | Davey et al.     | 07/26/94 |
|  |  | 5,417,719                  |  | Hull et al.      | 05/23/95 |
|  |  | 5,423,314                  |  | Schmid           | 06/13/95 |
|  |  | 5,439,440                  |  | Hofmann          | 08/08/95 |
|  |  | 5,449,378                  |  | Schouenborg      | 09/12/95 |
|  |  | 5,593,429                  |  | Ruff             | 01/14/97 |
|  |  | 5,649,936                  |  | Real             | 07/22/97 |

Examiner

Date Considered



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)**

COMPLETE IF KNOWN

|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

**Sheet 3 of 12**

|          |  | U.S. Patent or Application |  |                 |                 |
|----------|--|----------------------------|--|-----------------|-----------------|
|          |  | 5,682,233                  |  | Brinda          | 10/28/97        |
|          |  | 5,674,267                  |  | Mir et al.      | 10/07/87        |
|          |  | 5,810,762                  |  | Hofmann         | 09/22/98        |
|          |  | 5,861,015                  |  | Benja-Athon     | 01/19/99        |
|          |  | 5,873,849                  |  | Bernard         | 02/23/99        |
|          |  | 5,928,144                  |  | Real            | 07/27/99        |
|          |  | 5,941,845                  |  | Tu et al.       | 08/24/99        |
|          |  | 5,948,008                  |  | Daikuzono       | 09/07/99        |
|          |  | 5,968,063                  |  | Chu et al.      | 10/19/99        |
|          |  | 6,009,347                  |  | Hofmann         | 12/28/99        |
|          |  | 6,032,064                  |  | Devlin et al.   | 02/29/00        |
|          |  | 6,035,236                  |  | Jarding et al.  | 03/07/00        |
|          |  | 6,050,992                  |  | Nichols         | 04/18/00        |
|          |  | 6,068,650                  |  | Hofmann et al.  | 05/30/00        |
|          |  | 6,122,547                  |  | Benja-Athon     | 09/19/00        |
|          |  | 6,208,893                  |  | Hofmann         | 03/27/01        |
|          |  | 6,219,569                  |  | Kelly et al.    | 04/17/01        |
|          |  | 6,304,785                  |  | McCreery et al. | 10/16/01        |
|          |  | 6,341,237                  |  | Hurtado         | 01/22/02        |
|          |  | Des. 297,047               |  | Hon et al.      | 08/02/88        |
|          |  | Des. 318,330               |  | Doty et al.     | 07/16/91        |
|          |  | Des. 357,069               |  | Plahn et al.    | 04/04/95        |
|          |  | Des. 443,063               |  | Pisani et al.   | 05/29/01        |
| Examiner |  |                            |  |                 | Date Considered |



|   |  |                                    |
|---|--|------------------------------------|
|   |  | COMPLETE IF KNOWN                  |
|   |  | Application Number 09/928,044      |
|   |  | Confirmation Number 7172           |
| INFORMATION DISCLOSURE<br>STATEMENT BY APPLICANT<br>Form PTO-1449 (Modified)<br>(Use several sheets if necessary) |  | Filing Date August 11, 2001        |
|   |  | First Named Inventor Jon M. Bishay |
|   |  | Group Art Unit 3762                |
|   |  | Examiner Name George R. Evanisko   |
| Sheet 4 of 12   |  | Attorney Docket No. 000309.00202   |

### FOREIGN PATENT DOCUMENTS

|          |      | Foreign Patent or Application |             |            |                               | Date of Publication or | TRANSLATION<br>YESNO |  |
|----------|------|-------------------------------|-------------|------------|-------------------------------|------------------------|----------------------|--|
|          |      |                               |             |            |                               | Filing Date            |                      |  |
| Examiner | Cite | Kind Code                     |             |            | Name of Patentee or Applicant | of Cited               |                      |  |
| Initial  | No.  | Office                        | NUMBER      | (if known) | of Cited Document             | Document               |                      |  |
|          |      | FR                            | 2500309     |            | Faiveley                      | 08/27/82               | X                    |  |
|          |      | FR                            | 2500745     |            | Dervieux                      | 09/03/82               | X                    |  |
|          |      | GB                            | 2 163 355 A |            | Simonin                       | 02/26/86               |                      |  |
|          |      | GB                            | 2 255 719 A |            | Matthews                      | 11/18/92               |                      |  |
|          |      | WO                            | 01/39829 A1 |            | Vertis Neuroscience, Inc.     | 06/07/01               |                      |  |

### OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.           | PERTINENT |
|----------------------|-------------|---|-----------|
|                      |             | ASSOCIATION FOR ADVANCEMENT OF MEDICAL INSTRUMENTATION, "Implantable Peripheral Nerve Stimulators," American National Standard, ANSI/AAMI NS15 - 1995 pp. 1-8 NS15 - 1995 pp. 1-8   |           |
|                      |             | AHMED H. et al. "Percutaneous Electrical Nerve Stimulation (PENS): A Complementary Therapy for the Management of Pain Secondary to Bony Metastasis", The Clinical Journal of Pain (December 1998) Vol. 14, No. 4, pp. 320-3, Lippincott Williams & Wilkins, Philadelphia. |           |
|                      |             | AHMED H. et al. "Percutaneous Electrical Nerve Stimulation: An Alternative to Antiviral Drugs for Acute Herpes Zoster," Anesthesia & Analgesia (October 1998) 87: 911-4.  |           |

Examiner

Date Considered



INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)

COMPLETE IF KNOWN

Application Number 09/928,044  
Confirmation Number 7172  
Filing Date August 11, 2001  
First Named Inventor Jon M. Bishay  
Group Art Unit 3762  
Examiner Name George R. Evanisko  
Attorney Docket No. 000309.00202

Sheet 5 of 12

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.   | PERTINENT |
|-------------------|----------|---|-----------|
|                   |          | ALMAY, B.G.L. et al., "Long-Term High Frequency Transcutaneous Electrical Nerve Stimulation (hi-TNS) in Chronic Pain. Clinical Response and Effects on CSF Endorphins, Monoamine Metabolites, Substance P-Like Immunoreactivity (SPLI) and Pain Measures," Journal of Psychosomatic Research, (1985) Vol. 29, No. 3, pp. 247-257, Pergamon Press Ltd. Great Britain |           |
|                   |          | BAKER, L. L., et al. "Effects of Waveform on Comfort during Neuromuscular Electrical Stimulation," Clinical Orthopaedics and Related Research, August 1998, No. 223, pp. 75-85  |           |
|                   |          | BALLEGAARD, S. et al. "Acupuncture and Transcutaneous Electric Nerve Stimulation in the Treatment of Pain Associated with Chronic Pancreatitis. A Randomized Study", Scand. J. Gastroenterol. (June 1985) 20: 1249-54.  |           |
|                   |          | BALOGUN, J. et al. "The effects of acupuncture, electroneedling and transcutaneous electrical stimulation therapies on peripheral haemodynamic functioning", Disability and Rehabilitation (February 1998) Vol. 20, No. 2, pp. 41-8, Taylor & Francis Ltd.  |           |
|                   |          | BALOGUN, J., "Effects of Ramp Time on Sensory, Motor and Tolerance Thresholds during Exogenous Electrical Stimulation," The Journal of Sports Medicine and Physical Fitness, (December 1991) Vol. 31, No. 4, pp. 521-526  |           |
|                   |          | BD MICROTAINER Brand Safety Flow Lancet - Product Number 366356. BD catalog 1997-2000, <a href="http://catalog.bd.com/sctipts/OBDsheet.exe?FNC=productlist">http://catalog.bd.com/sctipts/OBDsheet.exe?FNC=productlist</a> Alistproducts.html 3 66356 (August 2001), 3 pages.   |           |
|                   |          | BD Safety Products. BD Vacutainer Safety-Lok Blood Collection Set; BD Vacutainer SafetyGlide Blood Collection Assembly and BD Vacutainer Eclipse Blood Collection Needle, 1 page.   |           |
|                   |          | BD Vacutainer SafetyGlide Blood Collection Assembly. Quick Reference Card (October 1999), 1 page.   |           |
| Examiner          |          | Date Considered   |           |





**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)**

*COMPLETE IF KNOWN*

|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |

**Sheet 6 of 12**

**Attorney Docket No. 000309.00202**

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.        | PERTINENT |
|----------------------|-------------|--|-----------|
|                      |             | BRULL, S. J., et al., "Pulse Width, Stimulus Intensity, Electrode Placement, and Polarity during Assessment of Neuromuscular Block," Anesthesiology, (October 1995) V. 83, No. 4, pp. 702-709, Lippincott-Raven Publishers   |           |
|                      |             | BUSHNELL M. C. et al. "Electrical stimulation of peripheral and central pathways for the relief of musculoskeletal pain", Can. J. Physiol. Pharmacol. (May 1991) 69: 697703.   | X         |
|                      |             | CARROLL, D. et al., "Randomization is Important in Studies with Pain Outcomes; Systematic Review of Transcutaneous Electrical Nerve Stimulation in Acute Postoperative Pain," British Journal of Anesthesiology, (1996) Vol. 77, pp. 798-803                           |           |
|                      |             | CASSUTO, J. et al., "The Use of Modulated Energy Carried on a High Frequency Wave for the Relief of Intractable Pain," International Journal of Clinical Pharm.Research (1993) XI II (4) pp. 239-241   |           |
|                      |             | CHENG R., POMERANZ, B. "Electroacupuncture analgesia could be mediated by at least two pain-relieving mechanisms: endorphin and non-endorphin systems", Life Sciences (December 1979) 25: 1957-62, Pergamon Press Ltd.   | X         |
|                      |             | CHENG R. et al. "Electroacupuncture elevates blood cortisol levels in naive horses; sham treatment has no effect", Intern. J. Neuroscience (February 1980) Vol. 10, pp. 95-7, Gordon and Breach Science Publishers, Inc., Great Britain.                               |           |
|                      |             | CHENG R. S. S., POMERANZ, B. "Electrotherapy of Chronic Musculoskeletal Pain: Comparison of Electroacupuncture and Acupuncture-Like Transcutaneous Electrical Nerve Stimulation", The Clinical Journal of Pain (1987) Vol. 2, No. 3, pp. 143-9, Raven Press, New York. | X         |
|                      |             | CRAMP, A.F.L. et al., "The Effect of High- and Low-Frequency Transcutaneous Electrical Nerve Stimulation Upon Cutaneous Blood Flow and Skin Temperature in Healthy Subjects," Clinical Physiology 20, (2000) 2, pp. 150-157, Blackwell Science Ltd.                    |           |
|                      |             | Empi Eclipse+ Dual Channel Transcutaneous Electrical Nerve Stimulator User's Manual, Empi, Inc. (September 1998), US Patent #D282,968, 31 pages.   |           |

Examiner

Date Considered



OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

|  |                          |                 |
|--|--------------------------|-----------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><b>Form PTO-1449 (Modified)</b><br>(Use several sheets if necessary) | <i>COMPLETE IF KNOWN</i> |                 |
|  | Application Number       | 09/928,044      |
|  | Confirmation Number      | 7172            |
|  | Filing Date              | August 11, 2001 |
|  | First Named Inventor     | Jon M. Bishay   |
|  | Group Art Unit           | 3762            |
| Examiner Name  | George R. Evanisko       |                 |
| Sheet 7 of 12  | Attorney Docket No.      | 000309.00202    |

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published. | PERTINENT |
|----------------------|-------------|---|-----------|
|                      |             | Empi EPIX VT Dual Channel Transcutaneous Electrical Nerve Stimulator Instruction Manual, Empi, Inc. (1997) 22 pages.  |           |
|                      |             | Empi EPIX XL TENS Instruction Manual, Empi, Inc. (September 1998) U.S. Patent No. D319,881, 22 pages.   |           |
|                      |             | Empi, Our Products: Electrotherapy for Rehabilitation, <a href="http://www.empi.com/b/b2.htm">http://www.empi.com/b/b2.htm</a> , (March 2001), 3 pages.   |           |
|                      |             | FOSTER, N.E., et al., "Manipulation of Transcutaneous Electrical Nerve Stimulation Variables Has No Effect on Two Models of Experimental Pain in Humans," The Clinical Journal of Pain, (1996) 12; pp. 301-310, Lippincott-Raven Publishers, Philadelphia       |           |
|                      |             | GADSBY, G. et al. "Nerve stimulation for low back pain - a review," Nursing Standard (July 1997) Vol. 11, No. 43, pp. 32-33.  |           |
|                      |             | GALLETI, S.P., et al., "Highlights in the Subject of Low Frequency-High Intensity TENS," Minerva Stomatologica (Italy) (Sept. 1995), 44, pp. 421-429  |           |
|                      |             | GHONAME, E. et al. "Does the Stimulus Frequency Affect the Analgesic Response to Electrical Stimulation?" Anesthesia & Analgesia (November 1999) 88: S210, Lippincott Williams & Wilkins.   | X         |
|                      |             | GHONAME, E. et al. "Percutaneous Electrical Nerve Stimulation for Low Back Pain", JAMA (March 1999) Vol. 281, No. 9, pp. 818-23.  | X         |
|                      |             | GHONAME, E. et al. "Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica", Pain (November 1999) 83: 193-9, Elsevier Science B.V.   | X         |
|                      |             | GHONAME, E. et al. "The Effect of Stimulus Frequency on the Analgesic Response to Percutaneous Electrical Nerve Stimulation in Patients with Chronic Low Back Pain", Anesthesia & Analgesia (October 1999) 88: 841-6.   | X         |

Examiner

Date Considered



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)

Page 8 of 12

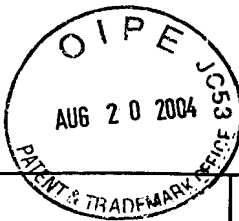
|                      |                    |
|----------------------|--------------------|
|                      | COMPLET F KNOWN    |
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

**OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.   | PERTINENT |
|----------------------|-------------|---|-----------|
|                      |             | GHONAME, E. et al. "The Effect of the Duration of Electrical Stimulation on the Analgesic Response", Anesthesia & Analgesia (January 1999) 88: S211.  | X         |
|                      |             | GOPALKRISHNAN, P., et al., "Effect of Varying Frequency, Intensity, and Pulse Duration of Transcutaneous Electrical Nerve Stimulation on Primary Hyperalgesia in Inflamed Rats," Arch. Phys. Med. Rehabil., (July 2000) Vol. 81, pp. 984-990  |           |
|                      |             | GRACANIN, F., et al., "Optimal Stimulus Parameters for Minimum Pain in the Chronic Stimulation of Innervated Muscle," Arch. Phys. Med. Rehabil. (June 1975) Vol. 56, pp. 243-249  |           |
|                      |             | HAMZA, M. et al. "Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain", Anesthesiology (December 1999), Vol. 91, No. 6, pp. 1622-7, Lippincott Williams & Wilkins, Inc.   |           |
|                      |             | HAMZA, M.A., et al., "Effect of the Frequency of Transcutaneous Electrical Nerve Stimulation on the Postoperative Opioid Analgesic Requirement and Recovery Profile," Anesthesiology, (Nov. 1999) V. 91, No. 5, pp. 1232-1238   |           |
|                      |             | HAN, J.S. et al., "Effect of Low- and High-Frequency TENS on Met-enkephalin-Arg Phe and dynorphin A immunoreactivity in human lumbar CSF," Pain, (1991) Vol. 47, pp. 295-298, Elsevier Science Publishers B.V.  |           |
|                      |             | Healthtronics HANS LY257 User Manual, Healthtronics Pte Ltd., Singapore, 15 pages.  |           |
|                      |             | Innovative Healthcare: Electrotherapy Pain & Rehabilitation Product Solutions from Rehabilicare. [Includes product description of SporTX and Ortho DX], <a href="http://www.mvpdesign.com/sites/rehabilicare/all_products.html">http://www.mvpdesign.com/sites/rehabilicare/all_products.html</a> , (August 2001), 3 pages. |           |
|                      |             | Intellect Legend Stim Clinical Reference Manual, Vol. 4 Intellect Legend Series, Chattanooga Group, Inc., (July 2000) 25 pages.   |           |

Examiner

Date Considered



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)

Sheet 9 of 12

COMPLETE IF KNOWN

|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

**OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.                           | PERTINENT |
|----------------------|-------------|---|-----------|
|                      |             | JETTE, D. U. et al., "Effect of Different Forms of Transcutaneous Electrical Nerve Stimulation on Experimental Pain," Physical Therapy, (February 1986) Volume 66/Number 2, pp. 187-193   | X         |
|                      |             | JOHNSON, M. I. et al., "Analgesic Effects of Different Pulse Patterns of Transcutaneous Electrical Nerve Stimulation on Cold-Induced Pain in Normal Subjects," Journal of Psychosomatic Research (1991) Vol. 35, No.2/3, pp. 313-321, Great Britain                                       |           |
|                      |             | JOHNSON, M. I. et al., "Analgesic Effects of Different Frequencies of Transcutaneous Electrical Nerve Stimulation on Cold-Induced Pain in Normal Subjects," Pain, (1989) 39, pp. 231-236, Elsevier Science Publishers B.V.  |           |
|                      |             | JOHNSON, M.I. et al., "An In-Depth Study of Long-Term Users of Transcutaneous Electrical Nerve Stimulation (TENS). Implications for Clinical Use of TENS," Pain (1991) 4, pp. 221-229, Elsevier Science Publishers B.V.   |           |
|                      |             | KATIMS, J.J. et al., "Transcutaneous Nerve Stimulation Frequency and Waveform Specificity in Humans," Appl. Neurophysiol. (1986) 49: pp. 86-91  | X         |
|                      |             | LANDAU, B. et al. "Neuromodulation Techniques for Medically Refractory Chronic Pain", Annu. Rev. Med. (February 1993) 44: 279-87, Annual Reviews Inc.   |           |
|                      |             | LEEM, J.W. et al., "Electrophysiological Evidence for the Antinociceptive Effect of Transcutaneous Electrical Stimulation on Mechanically Evoked Responsiveness of Dorsal Horns Neurons in Neuropathic Rats," Neuroscience Letters (1995) 192, pp. 197-200, Elsevier Science Ireland Ltd. |           |
|                      |             | LEHMANN T. et al. "Efficacy of Electroacupuncture and TENS in the Rehabilitation of Chronic Low Back Pain Patients", Pain (September 1986) 26: 277-90, Elsevier Science Publishers B.V.   | X         |
|                      |             | LISS, S. et al., "Physiological and Therapeutic Effects of High Frequency Electrical Pulses," Integrative Physiological and Behavioral Science, (April-June 1996) Vol. 31, No. 2, pp.88-94  |           |

Examiner

Date Considered



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)**

*COMPLETE IF KNOWN*

Application Number **09/928,044**  
 Confirmation Number **749s**  
 Filing Date **August 11, 2001**  
 First Named Inventor **Jon M. Bishay**  
 Group Art Unit **3762**  
 Examiner Name **George R. Evanisko**  
 Attorney Docket No. **000309.00202**

**Sheet 10 of 12**

**OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.  | PERTINENT |
|----------------------|-------------|--|-----------|
|                      |             | MARCHAND, S. et al., "Modulation of Heat Pain Perception by High Frequency Transcutaneous Electrical Nerve Stimulation (TENS)," The Clinical Journal of Pain (1991) 7: pp. 122-129, Raven Press Ltd., New York   |           |
|                      |             | Model AWQ-104B Multi-Purpose Electronic Acupunctoscope Instruction Manual, 10 pages.   |           |
|                      |             | MORENO-ARANDA, J. et al., "Electrical Parameters for Over-the-Skin Muscle Stimulation," J. Biomechanics, (1981) Vol. 14, No. 9, pp. 579-585, Pergamon Press Ltd.   |           |
|                      |             | MORENO-ARANDA, J. et al., "Investigation of Over-the-Skin Electrical Stimulation Parameters for Different Normal Muscles and Subjects," J. Biomechanics, (1981) Vol. 14, No. 9, pp. 587-593, Pergamon Press Ltd., Great Britain  |           |
|                      |             | O'BRIEN, W. J. et al., "Effect of Transcutaneous Electrical Nerve Stimulation on Human Blood B-Endorphin Levels," Physical Therapy, (September 1984) Volume 64/Number 9, pp. 1367-1374   |           |
|                      |             | OMURA, Y., "Basic Electrical Parameters for Safe and Effective Electro Therapeutics [Electro-Acupuncture, TES, TENMS, (or TEMS), TENS and Electro Magnetic Field Stimulation with or without Drug Field] for Pain, Neuromuscular Skeletal Problems, and Circulatory Disturbances," Acupuncture & Electro Therapeutics Res., Int. J. (1987) Vol. 12, pp. 201-225, Pergamon Journals Ltd., USA |           |
|                      |             | OMURA, Y., Electrical Parameters for Safe and Effective Electro-Acupuncture and Transcutaneous Electrical Stimulation: Threshold Potentials for Tingling, Muscle Contraction and Pain; and How to Prevent Adverse Effects of Electro-Therapy," Acupuncture and Electro-Therapeutics Res., Int. J., (1985) Vol. 10, Pergamon Press Ltd. USA   | X         |
|                      |             | ORDOG, G.J., "Transcutaneous Electrical Nerve Stimulation versus Oral Analgesic: A Randomized Double-Blind Controlled Study in Acute Traumatic Pain," American Journal of Emergency Medicine, (January 1987) Volume 5, Number 1, pp. 6-10  |           |

Examiner

Date Considered



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)**

**COMPLETE IF KNOWN**

|                      |                    |
|----------------------|--------------------|
| Application Number   | 09/928,044         |
| Confirmation Number  | 7172               |
| Filing Date          | August 11, 2001    |
| First Named Inventor | Jon M. Bishay      |
| Group Art Unit       | 3762               |
| Examiner Name        | George R. Evanisko |
| Attorney Docket No.  | 000309.00202       |

Sheet 11 of 12

**OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.                  | Pertinent? |
|----------------------|-------------|--|------------|
|                      |             | Pointer F-3 Instruction Manual, ITO Co., Ltd., Tokyo, Japan (1999), 12 pages.  |            |
|                      |             | Radionics products brochure. "A Significant Breakthrough Using Pulsed Radiofrequency for Pain Management", includes RF Lesion Generator System, Model RFG-3C Plus, (1997), Radionics, Burlington, MA, 10 pages.  |            |
|                      |             | Rehabicare Ortho Dx product brochure. "Reduce Rehabilitation Time and Enhance Patient Comfort with Ortho Dx", Rehabicare, New Brighton, MN, 2 pages.   |            |
|                      |             | Rehabicare SMP-plus product brochure. "SMP-plus. The Pain Relief Solution for Hard to Treat Patients", Rehabicare, New Brighton, MN (1999) 2 pages.  |            |
|                      |             | Rehabicare SporTX Product Data Sheet, 1 page.  |            |
|                      |             | Rehabicare SporTX Quick Set-Up Instructions, "SPORTX. Get back in the GAME!", Rehabicare, New Brighton, MN, 2 pages.   |            |
|                      |             | ROMITA, V.V. et al., "Parametric Studies on Electroacupuncture-Like Stimulation in a Rat Model; Effects of Intensity, Frequency, and Duration of Stimulation on Evoked Antinociception," Brain Research Bulletin, (1997) Vol. 42, No. 4, pp. 289-296, Elsevier Science Inc., USA | X          |
|                      |             | ROONEY, J.G. et al., "Effect of Variation in the Burst and Carrier Frequency Modes of Neuromuscular Electrical Stimulation on Pain Perception of Healthy Subjects," Physical Therapy, (November 1992) Volume 72, Number 11, pp. 800-809  |            |
|                      |             | SLUKA, K.A. et al., "Treatment with either High or Low Frequency TENS Reduces the Secondary Hyperalgesia Observed After Injection of Kaolin and Carrageenan into the Knee Joint," Pain, (1998) 77, pp. 97-102, Elsevier Science B.V.   |            |
|                      |             | SOMERS, D.L., et al., "High-Frequency Transcutaneous Electrical Nerve Stimulation Alters Thermal but not Mechanical Allodynia Following Chronic Constriction Injury of the Rat Sciatic Nerve," Arch. Phys. Med. Rehabil., (1998) 79, pp. 1370-1376                               |            |

Examiner

Date Considered



INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
Form PTO-1449 (Modified)  
(Use several sheets if necessary)

COMPLETE IF KNOWN

Application Number 091751,382  
Confirmation Number 7172  
Filing Date August 11, 2001  
First Named Inventor Jon M. Bishay  
Group Art Unit 3762  
Examiner Name George R. Evanisko  
Attorney Docket No. 000309.00202

Sheet 12 of 12

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published. | Pertinen |
|-------------------|----------|---|----------|
|                   |          | STAROBINETS, M. et al., "Analgesic Effect of High-Frequency and Acupuncture Like Transcutaneous Electric Stimulation of Nerve Fibers in Spinal Osteochondrosis," (Russian) Zhurnal Nevropatologii I Psikhiatrii Imeni S.S. Korsakova (1985) 85, (3) pp. 350-354 |          |
|                   |          | ULETT, G. et al. "Electroacupuncture: Mechanisms and Clinical Application", Biological Psychiatry (July 1998) 44: 129-38.   |          |
|                   |          | VAN DOREN, C.L., "Contours of Equal Perceived Amplitude and Equal Perceived Frequency for Electrocutaneous Stimuli," Perception and Psychophysics (1997) 59, (4), pp. 613-622   |          |
|                   |          | WHITE, P. et al. "Percutaneous Neuromodulation Therapy: Does the Location of Electrical Stimulation Effect the Acute Analgesic Response?", Anesthesia & Analgesia (October 2000) 91: 1-6.   | X        |
|                   |          | WHITE, P. et al. "The Effect of Montage on the Analgesic Response to Percutaneous Neuromodulation. Therapy" Anesthesia & Analgesia (February 2001) 92: 483-7.   | X        |
|                   |          | PCT International Search Report for International Application No. PCT/US01/31441; mailed 07 May 2002; Applicant: Vertis Neuroscience, Inc., 8 pages.  |          |
|                   |          | PCT International Search Report for International Application No. PCT/US02/25551; mailed 18 Feb 2003; Applicant: Vertis Neuroscience, Inc. 8 pgs  |          |

Examiner

Date Considered